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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,928	Applicant(s) BERTHON-JONES ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-28 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 34-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/4/05; 4/17/06; 6/29/06; 11/22/06; 4/4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 19-28 & 34-42 are pending in this application. Claims 1-18 & 29-33 have been cancelled as directed in applicants response filed April 4, 2008.

Election/Restrictions

2. Applicant's election without traverse of Group 1, Species 4 in the reply filed on April 4, 2008 is acknowledged.

Claim Objections

3. Claims 19-28 & 34-42 are objected to because of the following informalities:

In the claims, when the term "the" or "said" is used, the word following the term "the" or "said" must have proper antecedent basis. The terms "the" and "said" appear numerous times in the claims without proper antecedent basis for the limitations following the terms "the" and "said."

For example, Claim 19 recites the limitation "said selected frame portion" in line 5-6; however, there is insufficient antecedent basis for this limitation in the claim. Claim 19 provides antecedent basis for "said at least one selected portion" and applicant is reminded to be consistent in their terminology.

Claim 19 also lacks antecedent basis for "the position" and has improper antecedent basis for the second occurrence of "the selected frame portion" in lines 9-10.

Claims 20-24, 26-27 and 34 lack antecedent basis for claim limitations and they are objected to for reasons analogous to those of claim 1.

Claims 19 and 34 are also objected to because claim 19 capitalizes “Non-Invasive Positive Pressure Ventilation” whereas claim 34 does not. Applicant is requested to be consistent in their capitalization, or lack thereof, in the claims.

Any remaining claims are objected to as depending from an objected base claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 20 & 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Where a claim is directed to an apparatus attached to the human body or any part thereof the claim is directed to nonstatutory subject matter because the claim positively recites part of a human body. See: 1077 Official Gazette, April 21, 1987.

Claims 20 & 25 are rejected because they positively recite parts of a human body or a patient. Claim 20 claims “the force applied to the sides of the patient’s nose and/or face” and claim 25 claims “the cushion includes at least one inflatable element therein, to adjust an effective stiffness and/or an effective fit with the patient.” Apparatuses are “adapted to” be attached to a human.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19-28 & 34-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 & 34 are confusing because it is unclear if the frame includes the at least one aperture or if the main body includes the at least one aperture.

Claims 19-20, 22-24, and 27 are confusing because it is unclear if “the at least one selected portion” is the same “the selected frame portion” of claim 19, “the frame portion” and “said frame portion” of claim 20, “the selected frame portion” of claims 22-23; “the selected portion” of claim 24; and “the selected frame portion” of claim 27.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 19-20, 22-23, 27, and 34-42 rejected under 35 U.S.C. 102(a) as being anticipated by Amarasinghe et al., (WO 02/45784).

Regarding claim 19, Amarasinghe discloses a mask assembly (10) for application of Non-Invasive Positive Pressure Ventilation to a patient, comprising: a frame (figure 4) including a main body (13) including at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including at

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least one selected portion (12) provided to the main body, said selected [frame] portion being adjustable relative to the main body; and a cushion (16) provided to the frame, the cushion being structured to provide an interface with the patient (figure 2), said cushion, upon application of positive pressure, applying a force to the patient, said force being adjustable in accordance with 1) the position of the selected frame portion relative to the main body for a given value of said positive pressure (via the tightening of the straps as positive air flow pressure increases); and/or 2) variations in the positive pressure (as the positive air flow is increase, the straps will tighten and when the air flow is decreased to straps will loosen).

Regarding claim 20, Amarasinghe discloses a mask assembly with at least one headgear connector portion provided to the frame portion (15), said frame portion being movable in accordance with change in headgear strap tension to thereby adjust the force applied to the sides of the patient's nose and/or face in use (via adjusting the straps). See: figure 2.

Regarding claim 22, Amarasinghe discloses a mask assembly wherein the selected frame portion includes a flexible member supporting the cushion (15 supports the cushion by wrapping around it when the straps are fitted around a users head. See; figure 2.

Regarding claim 23, Amarasinghe discloses a mask assembly with a main body (13) and the selected frame portion (12) which are provided as two separate parts that are coupled to one another. See: page 6, line 27 –page 7, line 6 and figure 4.

Regarding claim 24, there is no structural limitation added to this claim. It is the examiner's position that the main body and the selected portion are moveable by a camming mechanism. Since a cam is merely a projecting part of a rotating wheel or shaft that strikes a lever at one or more points on its circular path, if a cam were to contact the mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism.

Regarding claim 27 Amarasinghe discloses a mask assembly with a selected frame portion that includes lateral sides of the frame that are made of a flexible material. See: page 7, lines 21-27.

Regarding claim 34, Amarasinghe discloses a mask assembly (10) for application of non-invasive positive pressure ventilation to a patient, comprising: a frame (figure 4) including a main body (13) including at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including a selected frame portion (12) provided to the main body, said selected frame portion being adjustable relative to the main body (it can be attached and detached from the 13); and a cushion provided to the frame (16), the cushion being structured to provide an interface with the patient (figure 2), wherein the cushion is adjustable in accordance with the position of the selected frame portion relative to the main body, and wherein the selected frame portion includes each lateral side of the frame (15), and the selected frame portion is bendable to cause each lateral side of the frame to push against sides of the cushion (12 is a bendable metal).

Regarding claim 35, Amarasinghe discloses a mask assembly with a selected

frame portion (12) that includes a flexible member (20) supporting the cushion. See: page 7, lines 8-20.

Regarding claim 36, Amarasinghe discloses a mask assembly wherein the main body is relatively stiffer than the flexible member. See: page 30, lines 29-30.

Regarding claim 37, Amarasinghe discloses a mask assembly with a main body (13) and a selected frame portion (12) that are provided as two separate parts that are coupled to one another. See: page 6, line 27 - page 7, line 6 and figure 4.

Regarding claim 38, Amarasinghe discloses a mask assembly wherein the selected frame portion (12) includes lateral sides of the frame (15) which are made of a flexible material (12 is a bendable metal).

Regarding claim 39, Amarasinghe discloses a mask assembly with a selected frame portion that is bendable about a longitudinal axis of the frame (12 is a bendable metal).

Regarding claim 40, Amarasinghe discloses a mask assembly with a selected frame portion (12) that includes side wing portions (15) which are movable relative to the main body to adjust the sides of the cushion (16).

Regarding claim 41, Amarasinghe discloses a mask assembly wherein each of the side wing portions are adjustable into a plurality of positions (12 which forms 15 is bendable).

Regarding claim 42, Amarasinghe discloses a mask assembly with a cushion that is adapted to provide a seal with the patient's nose (16 forms a seal with the user's face, which includes the user's nose).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 and 34 above, in view of Gradon et al., (2003/0089373).

Amarasinghe discloses all the limitations of claim 21 except the knob to change the relative positioning between the main body and the frame portion.

Gradon teaches a knob (440) that is used to adjust the bridge member (430). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask assembly disclosed by Amarasinghe by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon because of the reasonable expectation of obtaining a mask assembly that could be adjusted easily and quickly without having to undue the straps.

12. Claims 25-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 above, in view of Hellings et al., (5,975,079).

Amarasinghe discloses all the limitations of claims 25-26 and 28 except the cushion with an inflatable unit that adjusts the size of the nasal bridge and the element providing for multiple stiffening rates of the cushion .

Hellings teaches a mask that is curved and contoured around the mouth and nasal bridge with an inflatable cushion. The reference teaches applying the mask to a user's face and then inflating the cushion, to provide a pneumatic seal. See: col. 3, lines 48-65.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask disclosed by Amarasinghe by using an inflatable cushion as taught by Hellings, because of the reasonable expectation of obtaining a mask with a pneumatic seal while simultaneously alleviating orbital irritation and eliminating ocular pressure.

Regarding claim 28, the stiffening rate of the cushion taught by Hellings is directly attributable to the rate the gas is supplied to the mask. Thus, by adjusting the gas delivery rate, the cushion stiffening rate would also be adjusted. Thus, the combined references teach a cushion with at least one element providing for multiple stiffening rates as claimed.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McCall et al., (5,921,239); Amarasinghe et al., (2004/0065328); Kwok et al., (WO 00/78384 A1); Kwok et al., (6,112,746); Madaus et al., (2004/0025882); Eaton et al., (2004/0045551); Lovell (6,631,718); and Cannon (6,789,543) all of which are drawn to adjustable masks for delivering gasses to patient airways.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771